K100695

1 of 3

COLLAMATRIX Co. Ltd.

JAN 0 3 2013

510(k) summary

Summary information

1. **Date Prepared**

March 3, 2010

2. **Submitter name and address**

Collamatrix Inc.
1F, No.50-1, Keyan Road, Jhunan Science Park
Miaoli County, 350, Taiwan

3. **Contact person**

Name:	Dennis J. N. Seah
Tel:	+ 886 2 7711 3299
Fax:	+ 886 2 7711 3599

4. **Device names**

Propriety name:	CollaDental Barrier
Common name:	Collagen dental matrix
Classification name:	Dressing, Wound

5. **Device classification**

Regulatory class:	Barrier, Animal Source, Intraoral, Class II
Product code:	NPL

6. **Device description**

CollaDental Barrier is a nonfriable, resorbable membrane made of purified type I collagen derived from pig skin using standardized controlled manufacturing process. The collagen is obtained from veterinary certified pigs and purified to avoid its antigenicity. The manufacturing process complies with the standards for virus inactivation. The CollaDental

Barrier has been tested for purity using standard purity testing procedures, sterilized by gamma irradiation and for single use only. It is flexible and conforms to the contours of the defect site. When moistened with water, saline, serum or blood, the device is flexible and conforms to the contours of the defect site. CollaDental Barrier has not been tested on persons less than 18 years of age.

7. Intended use

CollaDental Barrier is intended for use in oral surgical procedures including use in augmentation around implants placed in immediate extraction sockets, delayed extraction sockets; filling of bone defects after roots resection, cystectomy, removal of retained teeth; guided bone regeneration in dental implant associated bony dehiscence defects and guided tissue regeneration procedures in bony dehiscence defects around teeth.

8. Statement of Substantial equivalence

CollaDental Barrier is a device similar to predicate devices that are previously approved by the agency. CollaDental Barrier is substantially equivalent in indications and design principles to predicate devices, BioMend Extend absorbable collagen membrane (K992216) and BIO-GIDE® (K042197), each of which has been determined by FDA to be substantially equivalent to preamendment devices. CollaDental Barrier has the following similarities to the predicate devices in terms of indication for use, technological characteristics, material use and the process for sterilization. In summary, CollaDental Barrier is substantially equivalent to the predicate devices under the 510(k) regulations.

9. Biocompatibility

CollaDental Barrier has been demonstrated to be safe. To support the biocompatibility of this product, safety tests were conducted in accordance with ISO 10993 Part 1 Biological Evaluation of Medical Devices.

All test results from tests conducted on CollaDental Barrier are taken together as a whole, CollaDental Barrier have been demonstrated to be a safe device in accordance with ISO 10993-1.

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COLLAMATRIX Co. Ltd.

10. Conclusion

CollaDental Barrier is essentially equivalent in indication for use, technological characteristics and material to the commercially available predicate device, and therefore meets the requirements as defined in 21 CFR § 807.

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 3, 2013

Mr. Dennis J.N. Seah
Collamatrix, Incorporated
26F No. 105, Section 2 Dunhua
South Road, DA-AN Distric
Taipei, China 106

Re: K100695
Trade/Device Name: CollaDental Barrier
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPL
Dated: January 5, 2011
Received: December 14, 2012

Dear Mr. Seah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA 2013.01.03 08:32:49 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100695

Statement of indications for use

510(K) Number (if known): K100695

Device Name: CollaDental Barrier

Indications for Use:

CollaDental barrier is intended for use in oral surgical procedures including use in augmentation around implants placed in immediate extraction sockets, delayed extraction sockets; filling of bone defects after roots resection, cystectomy, removal of retained teeth; guided bone regeneration in dental implant associated bony dehiscence defects and guided tissue regeneration procedures in bony dehiscence defects around teeth.

Prescription Use__X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.12.31 10:48:45 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100695